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09/936,179	09/10/2001	Satoru Okamoto	213701US0PCT	9582

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EXAMINER.

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 12/12/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/936,179

**Applicant(s)**

OKAMOTO ET AL.

**Examiner**

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-14 is/are pending in the application.
- 4a) Of the above claim(s) 8-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

***Election/Restrictions***

Newly submitted claims 8-14 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: these claims recite a step of determining a peptide and preparing said peptide i.e., step d, which is not originally presented. Also, the species of biomolecule such as the nucleic acid and sugar.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 8-14 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Status of Claims***

Claims 1 and 3-14 are pending in the application.

Claim 2 has been cancelled in the Amendment of 9/22/03.

Claims 8-14 are withdrawn, as stated above.

Claims 1 and 3-7 are under examination.

***Specification***

The objection to the abstract of the disclosure has been obviated with the submission of a new abstract.

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***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35

U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method utilizing a phage random peptide library of structure as recited in e.g., page 29 and a substance that inhibits a nonstructural protein 3, HCV serine protease (NS3 protease) as the biomolecule with E.coli as the organism does not reasonably provide enablement for a method of screening any type of substance that interacts with any biomolecule using any type of peptide library or organism. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for reasons advanced in the last Office action.

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***Response to Arguments***

Applicants argue that the claims have been amended to define the biomolecule as being selected from a protein, a nucleic acid or a sugar chain. The biomolecule is reasonably expected to interact with a peptide. Applicants submit several references to show that the method for detecting an interaction between the biomolecule and a peptide-presenting phage library are known. Applicants further cite the art of record e.g., Martens to show enablement of phage display and interaction of the biomolecule with peptides. Applicants direct the examiner's attention to MPEP 2142.02 which states that the specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation.

In response, the recitation of these different biomolecules does not obviate this rejection as the specification enables only peptides for said biomolecule. The newly submitted references clearly disclose interactions of specific components under specific conditions as applied to said specific components. The newly cited references do not suggest or even implicitly state that the specific components employed therein can be extrapolated to the broad scope of e.g., biomolecules, organisms, peptide library, a chemical organic library and etc.

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Applicants appear contradictory in citing the art of record. As applicants state at page 9, for example, of the instant REMARKS Martens fail to disclose or suggest a step of testing inhibitory effect of a substance. This inhibitory substance is but only one of the numerous undefined variables encompassed by the broad claimed scope.

The MPEP section while not requiring examples however, clearly indicates that the specification must disclosed enabling disclosure that would lead one skilled in the art to the broad claimed scope without undue experimentation. Thus, the specification is replete with generalized statements but the exemplification or applicability to specifics is lacking. Because the art is unpredictable, applicants' specification reasonably would not have assured persons skilled in the art that the numerous undefined variables would display an inhibitory peptide that inhibits a binding biomolecule without undue experimentation. Applicants do not adequately enable persons skilled in the art to readily determine such. Applicants need not guarantee the success of the full scope of the claimed invention. However, skilled artisans are provided with little assurance of success.

[It is suggested that applicants recite the biomolecule as the HCV as recited in the EXAMPLES].

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Claims 1, 3-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The as-filed specification does not provide a description of the step d, as amended and a substance selected from a chemical compound library. The original disclosure does not disclose step d with the broad chemical compound library, as presently claimed. Applicants point out support at pages 4-51 i.e., the entire disclosure. However, MPEP 714.02 recites that applicants point out where **specifically** support is found for the newly presented limitation. Furthermore, the disclosure does not describe a chemical compound library, how to make said chemical compound library, the chemical compounds encompassed by said library. More importantly how said library is tested as having an inhibitory effect against the biomolecule and peptides expressed from the recombinant organisms.

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***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants' amendments to the claims have overcome the 112, second paragraph rejection of record. However, the following rejections apply to the newly amended claims.

Newly amended claims 1 and 3-7 are rejected under 35 USC 112, second paragraph as follows:

1. The recited "a step" in each of steps a-e is redundant and merely makes the claim confusing. The recitation in the preamble comprising of the following "steps" suffices. Also, this claim is confusing as being unclear as to whether contacting and/or selecting is between the biomolecule and the peptide library expressed by the organisms or between the biomolecule and the library of organisms. It is not clear as to the step of testing the inhibitory effect of a substance.



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2. Claims 3 and 4 are confusing with the recitation that the peptide library is a random peptide-presenting E. coli library.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3 and 5-6 rejected under 35 U.S.C. 102(b) as being anticipated by Martens et al (The Jrnl. of Biological Chemistry) for reasons set forth in the previous Office action.

***Response to Arguments***

Applicants' argue that Martens is silent with respect to steps (d) and (e).

In response, the disclosure of Martens reciting he inhibitors to the binding of the ligand to the biomolecule as E-selectin indicates that such testing would inherently have occurred that afford the inhibitory effect of the inhibitor.

Applicants' further arguments simply reiterate the scope of what is claimed. Accordingly, the specific method steps of

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Martens using specific components of the E-selectin and its ligand with determining the effect of the inhibitor against the binding of the ligand to E-selectin receptors fully meets the broad scope of claimed method.

Claims 1 and 3-7 are rejected under 35 U.S.C. 102(b) as being anticipated O'Neill et al (Proteins) for reasons of record.

#### ***Response to Arguments***

The response above is applied herein since applicants' arguments are directed to the same argument under Martens above.

The rejection of claims 1-6 over Klein is withdrawn in view of the amendments to the claims and applicants' arguments.

#### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action

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is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

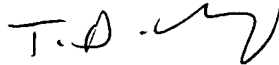
This application contains claims 8-14, species nucleic acid and sugar drawn to an invention nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. TWessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flextime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
T. D. Wessendorf  
Primary Examiner  
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tdw  
December 10, 2003